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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,797	09/18/2003	Liaoteng Wang	960296.99314	6746

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,797	WANG ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *2,4,8,10 and 12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/09/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-28 are pending.

Response to restriction requirement filed 11/27/2006 is acknowledged. Applicant elected, without traverse, Group IA, directed to polymerase comprising a catalytic and RNA-binding subunit. Claims 2, 4, 8, 10, 12-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Claims 1,3,5,6,7,9,11 are under consideration.

Sequence Listing

2. The Sequence Listing was approved by STIC for matters of form.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3,9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

Claims 3,9: The term GLD-3 is vague and indefinite. Specification, while addressing protein abbreviated as "GLP-3" does not provide structure and sequence of the protein and one skilled in the art will not understand the meaning of the term and will not be appraised of the scope of the invention. The reference of Eckmann, C. R (Cell Dev., Volume 3, Issue 5 , November 2002, Pages 697-710) cited in the specification ([0006]) is post-filing.

The same applies to other "RNA-binding" proteins, GIP-1, and GIP-2, addressed in claim 9.

Claim Rejections - 35 USC § 112, first paragraph (enablement).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1,9,11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for regulatory poly(A)polymerase (rPAP) comprising particular catalytic subunit, GLD-2 (SEQ ID No. 5) or homologs or mutants thereof, does not reasonably provide enablement for rPAPs having undefined "catalytic subunit". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The scope of the claims encompass any protein described, functionally, as having poly(A) polymerase activity, and structurally as comprising two subunits, catalytic and RNA-binding subunits. The issue of catalytic subunit is addressed in this rejection.

Specification teaches that, functionally, the catalytic subunit has same enzymatic activity as GLD-2 ([0033]). It is not clear what core structure, if any, is required for the product claimed generally as in claim 1, to have the functional activity as GLD-2. Structurally, the catalytic subunit is addressed as having "the three catalytic carboxylates" and the "residues required for positioning the nucleotide". Neither which "three catalytic carboxylates" are meant nor which residues are required for what "positioning" of which "nucleotide" is defined in the specification. Further, the definition of the catalytic subunit requires said (undefined) residues to be located "in order" and with the approximate spacing as that presented in Fig.11 ([0033]). While the latter description is understandable with respect to GLD-2 and its homologs, it does not clarify the ambiguities mentioned before that regarding "a catalytic unit" in general. The other identified catalytic subunits, such as Hs-1 (SEQ ID No. 7) and Mm-1 (SEQ ID no. 8) are both homologs of the same GELD-2 protein.

Prior art teaches examples of cytoplasmic regulatory poly(A)polymerase but does not provide guidance for general structure of such enzymes. Thus, Saitoh et al. (see IDS) teaches Cid13 cytoplasmic poly(A)polymerase, which is structurally different from GLD-2 (see Fig. 1).

The skilled practitioner would first turn to the instant specification for guidance in practicing the full scope of the claimed method, however the specification only provides guidance to GLD-2 and homologs thereof. As such the practitioner would turn to the prior art for such guidance, however the prior art does not provide guidance for structure

of "catalytic subunit" in general. Finally, said practitioner would turn to trial and error experimentation to discover sequences that have functional features as claimed without guidance from the specification or the prior art. Such represents undue experimentation.

5. Claims 1,5-7,11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for regulatory poly(A)polymerase (rPAP) comprising particular RNA-binding subunits, as addressed in claim 9, does not reasonably provide enablement for rPAPs having undefined "RNA-binding catalytic subunit".

Similarly to the issue of catalytic subunit, with respect to the RNA-binding subunit, specification teaches that "the RNA-binding subunit recruits the catalytic subunit to an RNA, and thereby stimulates its activity" (paragraph [0037]). The three proteins addressed as RNA-binding subunit, GLD-3, GIP-1, and GIP-2, are not demonstrated to have any common structure, and specification does not identify any commons structure required for a protein to be a RNA-binding subunit.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 112, first paragraph (written description).

6. Claims 1, 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims encompass a genus of proteins described, functionally, as having poly(A) polymerase function, and structurally as comprising two subunits, catalytic and RNA-binding subunits.

For claims drawn to a genus, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 and MPEP 2163.II.A.3.(i).

In the instant case, the catalytic subunit poly(A) polymerase is disclosed as being a particular protein, GLD-2 or homologs thereof. See p. 13, paragraphs [0034]-[0035]. There is no disclosure of structure of a catalytic subunit of a poly(A) polymerase in general, other than related to GLD-2. Further, the functional language of being a poly(A) polymerase is not sufficient identifying characteristic to show that the applicant was in possession of the claimed genus of any cytoplasmic poly(A) polymerase.

Claim Rejections - 35 USC § 102 and 103.

7. Because sequence of RNA-binding subunits is not disclosed in the instant specification (see rejection under 35 U.S.C. 112, second paragraph, above), sequence search of particular RNA-binding subunits has not been carried out. References teaching catalytic subunits are listed in Prior Art of Record section below. The following rejection addresses broad claims.

8. Claims 1,11 are rejected under 35 U.S.C. 102(a) as anticipated by Saitoh et al (Cell, 109, 563-573, 2002; reference submitted by appicant).

Saitoh teaches cytoplasmic poly (A) polymerase which contains catalytic subunit Cid13 (see abstract, and p. 569, right column), and is considered to be representative of a class of cytoplasmic poly (A) polymerases (p. 569, left column, bottom). In addition, Cid13 is taught as being associated with a binding protein (p. 568, left column).

9. Claims 1,11 are rejected under 35 U.S.C. 102(b) as anticipated by Dickson et al. (J. Biol. Chem, 10.1074/jbc.M103030200; published online September 10, 2001)
Dickson teaches complex of a "cleavage and polyadenylation specificity factor" (CPSF), "cytoplasmic polyadenylation element binding protein" (CPEB), which has specificity of cytoplasmic polyadenylation of some mRNAs and is implicated in cytoplasmic polyadenylation in *X. laevis* oocytes

Prior art made of record

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

SEQ ID No. 5, i.e., GLD-2, was reported as "Defective in germ line development protein 2, isoform, a (Regulatory cytoplasmic polyA polymerase)" in database SwissProt, Accession Number O17087, Integrated into TrEMBL on 1998-01-01 and published in Science, 282, 2012-2018, 1998 "The C. elegans sequencing consortium. Genome sequence of the nematode C. elegans: a platform for investigating biology."(PubMed: 9851916; Medline: 99069613).

SEQ ID No. 7, i.e., hS-1, is disclosed in PNAS, 24, 2002, vol. 99, no. 26,16899-16903; this sequence is integrated into UniProtKB/TrEMBL as Assession Number AC Q91YI6 on 01/12/2001.

SEQ ID No. 8, i.e., Mm-1, is disclosed in PreGrant Publication 20040005560 (filing date 03/28/2002) as SEQ ID No.3366

Conclusion.

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571)272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb